

What is claimed is:

520-250 1. A substantially purified antigenic polypeptide subunit of Urinary Tumor Associated Antigen having, after reduction by  $\beta$ -mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis, a molecular weight of about 90 to 100 kD.

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520-387 2. A monoclonal antibody produced by isolating antibody producing cells from an animal exposed to the polypeptide of claim 1, forming hybridomas between the antibody producing cells and cancer cells, and selecting cells which produce antibodies reactive with the polypeptide.

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3. A method of detecting a cancer in a subject comprising contacting Urinary Tumor Associated Antigen from the subject's body fluid with the monoclonal antibody of claim 2 and detecting the presence of the bound antibody, the presence of Urinary Tumor Associated Antigen indicating the presence of a cancer.

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4. The method of claim 3, wherein the cancer is subclinical.

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520-387 5. The monoclonal antibody of claim 2, wherein the monoclonal antibody is selected from the group consisting of IgG and IgM.

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6. Reagents which are reactive with antibodies which are reactive with Urinary Tumor Associated Antigen.

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520-387 7. Reagents of claim 6, wherein the reagents are anti-idiotypic antibodies.

424-85.8  
8. A method of immunotherapy comprising injecting in a subject a therapeutic amount of the anti-idiotypic antibodies of claim 7.

9. A method for monitoring a malignancy comprising contacting Urinary Tumor Associated Antigen from a body fluid of an afflicted subject with the monoclonal antibody of claim 2, determining the amount of Urinary Tumor  
5 Associated Antigen per a given amount of body fluid, comparing the amount with an amount previously determined for an equivalent sample, a variation in Urinary Tumor Associated Antigen indicating a variation of the state of the malignancy.

10. A method of detecting Urinary Tumor Associated Antigen on tumor cells of a biopsy comprising contacting the tumor cells with the monoclonal antibody of claim 2 and detecting the presence of the bound antibody.

424-88  
11. A vaccine for inducing or enhancing antibodies or cell mediated immunity directed against a tumor cell, comprising inactivated tumor cells having a Urinary Tumor Associated Antigen on the cell surface and at least one tumor  
5 associated antigen selected from the group consisting of GM-2, GD-2, Fetal Antigen, or Melanoma-Tumor Associated Antigen, and a pharmaceutically acceptable carrier.

12. The vaccine of claim 11, wherein the tumor cells are melanoma cells selected from the group consisting of UCLA-SO-M10, UCLA-SO-M24 and UCLA-SO-M101.

13. The vaccine of claim 11, wherein the <sup>tumor</sup> cells further have HLA of the same type as that of the subject on the cell surface.

- 124-88
14. A method for inducing or enhancing in a subject the production of antibodies reactive with the polypeptide subunit of Urinary Tumor Associated Antigen having a molecular weight of about 90 to 100 kD after reduction by
- 5 B-mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis comprising administering to the subject an effective dose of the vaccine of claim 11.

15. The method of claim 14, wherein the subject is a human being.

16. The method of claim 14, wherein the subject is afflicted with a cancer and the antibody produced in the individual after administration of the vaccine inhibits the cancer.

17. The method of claim 16, wherein the cancer is selected from the group consisting of a melanoma, sarcoma and carcinoma.

Sub-B1

18. A vaccine comprising the polypeptide<sup>subunit</sup> of claim 1 and a pharmaceutically acceptable carrier.

19. A method for inducing or enhancing in a subject the production of antibodies reactive with tumor cells in the subject comprising administering the vaccine of claim 18.

ASSAYS  
A35/2

20. A method of detecting a breast or lung carcinoma in a subject comprising detecting the presence of Urinary Tumor Associated Antigen from a sample of the subject.

21. The method of claim 20, wherein the detection comprises binding the Urinary Tumor Associated Antigen with an antibody and detecting the presence of the antibody.

424-85-8  
424-85-9  
22. A method of in vivo detection of a tumor in a subject, comprising injecting into the subject a reagent reactive with Urinary Tumor Associated Antigen on the tumor cell surface, detecting the presence of the reagent which reacts with the Urinary Tumor Associated Antigen and thereby detecting the tumor.

23. The method of claim 22, wherein the tumor is selected from the group consisting of a melanoma, sarcoma, or carcinoma.

24. The method of claim 23, wherein the reagent is an antibody.

25. The method of claim 24, wherein the antibody is monoclonal.

424-85-8  
424-85-9  
26. A method of inhibiting a tumor expressing Urinary Tumor Associated Antigen on the tumor cell surface in a subject comprising injecting into the subject a tumor inhibiting reagent reactive with Urinary Tumor Associated Antigen on the tumor cell surface.

27. The method of claim 26, wherein the reagent is an antibody.

28. The method of claim 27, wherein the antibody is attached to a cytotoxic or cytostatic agent.

29. The method of claim 28, wherein the cytotoxic or cytostatic agent is selected from the group consisting of a toxin, radiolabeled moiety and chemotherapeutic agent.

526-27  
30. A nucleic acid encoding the polypeptide of claim 1.

✓ 31. A nucleic acid probe capable of selectively hybridizing with the nucleic acid of claim 30.

✓ 32. A nucleic acid encoding an antigenic portion of the polypeptide of claim 1.

✓ 33. The nucleic acid of claim 32, wherein the nucleic acid corresponds to an antigenic-sequence on an anti-idiotypic antibody.

✓ 34. A nucleic acid probe capable of selectively hybridizing with the nucleic acid of claim 33.

435/7  
ASSAYS  
35. A method for detection of low levels of Urinary Tumor Associated Antigen comprising enhancing the expression of Urinary Tumor Associated Antigen on cancer cells with gamma-interferon, contacting the Urinary Tumor Associated Antigen with a reagent and detecting the presence of the reagent.

36. A method of diagnosing a cancer in a subject comprising detecting the polypeptide of claim 1 in a subject's body fluid.

37. The method of claim 36, wherein the detecting comprises contacting the polypeptide with a reagent and detecting the presence of the reagent which is reactive with the polypeptide.

38. A method of detecting or monitoring a cancer in a subject having a urinary antigenic complex resulting from the cancer comprising:

- 5 (1) removing a sample from the subject;

(2) altering the carbohydrate portion of the urinary antigenic complex in the sample so as to prevent binding with reagents which bind to Urinary Tumor Associated Antigen; and

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(3) detecting at least a portion of the altered urinary antigenic complex and thereby detecting the cancer.

570-024  
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✓ 39. An epitope of Urinary Tumor Associated Antigen located on the 45 kD polypeptide subunit after reduction by  $\beta$ -mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis and reactive with autologous human serum or baboon polyclonal antibody. ✓

✓ 40. An epitope of Urinary Tumor Associated Antigen located on the 120 kD polypeptide subunit after reduction by  $\beta$ -mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis and reactive with baboon polyclonal antibodies. ✓

41. A method of detecting Urinary Tumor Associated Antigen in a sample comprising:

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(1) contacting the Urinary Tumor Associated Antigen with a first reagent which binds to an epitope on Urinary Tumor Associated Antigen;

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(2) contacting the Urinary Tumor Associated Antigen with a second reagent which binds to a second epitope on Urinary Tumor Associated Antigen;

(3) binding one of the reagents to a solid support; and

(4) detecting the presence of the bound reagent and thereby detecting the presence of Urinary Tumor Associated Antigen,  
5 wherein one of the reagents is a non-human polyclonal antibody.

42. The method of claim 41, wherein both of the reagents are antibodies.

43. The method of claim 41, wherein the polyclonal antibodies are isolated from a baboon.

44. The method of claim 41, wherein the reagent is bound to the solid support prior to binding to an epitope on Urinary Tumor Associated Antigen.

45. A method of detecting Urinary Tumor Associated Antigen in a sample comprising:

(1) contacting the Urinary Tumor Associated Antigen with a first reagent which binds to an epitope on Urinary Tumor Associated Antigen selected from the group consisting of the epitope on the 45, 65, 90-100 and 120 kD subunit as identified after reduction by  $\beta$ -mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis;

(2) contacting the Urinary Tumor Associated Antigen with a second reagent which binds to a second epitope on Urinary Tumor Associated Antigen selected from the group consisting of the epitope on the 45, 90-100 and 120 kD subunit as identified after reduction by  $\beta$ -mercaptoethanol and separation by SDS-polyacrylamide gel electrophoresis.

(3) binding one of the reagents to a solid support;  
and

(4) detecting the presence of the unbound reagent and  
thereby detecting the presence of Urinary Tumor  
Associated Antigen.

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46. An epitope of Urinary Tumor Associated Antigen located  
on the 65 kD polypeptide subunit after reduction by  $\beta$ -  
mercaptoethanol and separation by SDS-polyacrylamide gel  
electrophoresis and reactive with autologous human serum or  
baboon polyclonal antibody.

add  
B2

add  
C3

add  
D2

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E1

add  
F2

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G3